

Notice of Allowability	Application No.	Applicant(s)	
	09/756,070	TAYLOR, PAUL D.	
	Examiner	Art Unit	
	Jehanne Souaya Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to not applicable.
2. ☒ The allowed claim(s) is/are 1-30,33-42,64, 66-68, and 72.
3. ☒ The drawings filed on 06 January 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>12/19/2002</u> | 7. <input type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

Upon withdrawal from issue, the instant application was assigned to examiner Jehanne Sitton. Please direct all future correspondence regarding the instant application to examiner Sitton.

The amendment filed on 12/18/2003 under 37 C.F.R. 1.312 has been entered.

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance: The claims are drawn to methods of separating heteroduplex and homoduplex DNA molecules in a mixture by applying the mixture to an anion exchange solid and eluting the solid with a mobile phase comprising an eluting salt, a buffer, and optionally an organic solvent (claim 29 does not require an organic solvent), wherein the eluting results in the separation of the heteroduplexes from the homoduplexes. On 6/9/2003, an office action rejected the majority of the claims as obvious over Ohmiya et al in view of Gjerde et al (see section 6 of office action). Additional references were used to reject more specific dependent claims. In a response filed 10/9/2003, applicants asserted that the Gjerde et al reference did not qualify as art under 35 USC 103(c) because the Gjerde et al reference was commonly assigned with the instant application and only qualified as prior art under 35 USC 102(e), (f), or (g). In the next communication from the examiner (11/24/2003) the rejections using Gjerde et al were withdrawn (all rejections) and the instant application was allowed. Upon further review, however, it was determined that the basis for withdrawal of the rejections was incorrect because in fact, the Gjerde et al reference (US Patent, 5,972,222, issued

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10/26/1999) also qualified as prior art under 35 USC 102(a), and therefore could not be excluded under 103(c). The instantly pending claims, however, are allowable for the reasons that follow.

The closest prior art, as stated in the first office action (6/9/2003), is Gjerde et al and Ohmiya et al. Gjerde et al teaches separation of homoduplex DNA from heteroduplex DNA in a mixture by applying the mixture to a DNASep column and eluting with an acetonitrile gradient. Gjerde et al, however, does not teach or suggest separation of homoduplex DNA from heteroduplex DNA in a mixture by applying the mixture to an anion exchange solid in a chromatographic method, and further does not teach or suggest eluting with a salt and a buffer. The 6/9/2000 office action points to column 1, lines 39-49 as a suggestion by Gjerde et al of applying "the mixture [homoduplex and heteroduplex DNA mixture] to an anion-exchange solid" (see page 4, 2nd para of office action). However, a thorough review of the Gjerde et al reference as well as references cited by Gjerde et al, shows that Gjerde et al does not suggest or teach applying a heteroduplex/homoduplex mixture of DNA to an anion exchange solid nor the separation of heteroduplex and homoduplex DNA in a mixture using anion exchange chromatography, but rather that at column 1, lines 39-49, Gjerde et al teaches the general background of the art which was that length relevant separation of polynucleotide fragments was possible using anion exchanger separation media using tetramethylammonium chloride, tremethylammonium groups, and that anion exchangers with DEAE groups had been used to separate polynucleotide fragments. The method of Gjerde et al at example 7, involves the separation of heteroduplex and homoduplex DNA in a mixture using an inorganic substrate which supports non-polar material (ie: polystyrene/divinylbenzene) and that any residual polar groups are capped (see para bridging col 2-col 3, and example 7). Such chromatography is also

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known as Matched Ion Polynucleotide Chromatography). Gjerde et al, however, never teaches or suggests that the non-polar solid used for MIPC chromatographic separation is equivalent or comparable in properties to an anion exchange resin that is inherently polar and contains ionic groups bound to the surface of the resin. Ohmiya et al teaches separating DNA molecules and their fragments using an anion-exchange solid. Ohmiya et al, however does not teach or suggest separation of heteroduplex and homoduplex DNA in a mixture using an anion-exchange solid. The instant claims, are therefore allowable over the closest prior art. Additionally, none of the secondary references used in the rejections made under 35 USC 103(a) in the 6/9/2003 office action teach or suggest methods of separating heteroduplex and homoduplex DNA molecules in a mixture by applying the mixture to an anion exchange solid and eluting the solid with a mobile phase comprising an eluting salt and a buffer, wherein the eluting results in the separation of the heteroduplexes from the homoduplexes.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571) 272-0782. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.



Jehanne Sitton
Primary Examiner
Art Unit 1634

7/21/04